UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,620	02/04/2004	Jonathan M. Graff	UNI919/4-8US	9412

7590 12/02/2005

M. Michelle Muller
VINSON & ELKINS LLP
2300 First City Tower
1001 Fannin
Houston, TX 77002-6760

EXAMINER	
KAPUSHOC, STEPHEN THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,620	GRAFF ET AL.	
	Examiner	Art Unit	
	Stephen Kapushoc	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

There appears to be inconsistency in the claim numbers of base claims that are referred to in various dependent claims. For the purpose of this restriction requirement, the examiner has assumed that the following dependent claims should in fact refer to the following base claims: claim 7 should refer to claim 6; claims 10-12 should refer to claim 9, claim 16 should refer to claim 15, claim 17 should refer to claim 16, claims 19-25 and 30-31 should refer to claim 18, claims 26-29 should refer to claim 25, claim 32 should refer to claim 31, claim 33 should refer to claim 32, claims 35-40 should refer to claim 34, claims 42-43 should refer to claim 41, claims 45-46 should refer to claim 44, claims 48-49 should refer to claim 47.

Applicant should either affirm that the claims are correct as currently written, or amend the claims for correction and file amended claims.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-3, 6-8, 18-20, 22-24, 34-36, and 38-40 in part as they apply to nucleic acid based methods, and claims 4,5, 9-13, and 25-30 in their entirety, drawn to nucleic acid based methods for diagnosing, assessing prognosis, and monitoring progression of breast or ovarian cancer, classified in class 435, subclass 6.

   II. Claims 1-3, 6-8, 18-20, 22-24, 34-36, and 38-40 in part as they apply to protein based methods, and claims 14-17, 21, 31-33 and 37 in their

entirety drawn to protein based methods for diagnosing, assessing prognosis, and monitoring progression of breast or ovarian cancer, classified in class 435, subclass 7.1.

III. Claims 41-43, drawn to methods for assessing a test compound, classified in class 436, subclass 501.

IV. Claims 45 and 48, drawn to kits for diagnosing a disease or assessing the suitability of a test compound based on nucleic acid analysis, classified in class 536, subclass 23.1.

V. Claims 46 and 49, drawn to kits for diagnosing a disease or assessing the suitability of a test compound based on protein analysis, classified in class 514, subclass 2.

VI. Claim 50 in part as it applies to an agent that binds a gene product, and claims 51 and 52 in their entirety, drawn to therapeutic agents that bind to gene products, classified in class 514, subclass 2.

VII. Claim 50 in part as it applies to an agent that binds nucleic acid and claims 53-55 in their entirety, drawn to therapeutics that bind to nucleic acids, classifiable in class 514, subclass 44.

Further restriction requirement:

2. Applicant shall further select a single disease (either breast cancer or ovarian cancer) and further select a single genetic marker (either CXCL9 or FLJ20174) for examination. Claims will only be examined to the extent that they address the selected disease, and only to the extent that they require the selected genetic marker and its associated SEQ ID NOs. For example, if applicant elects the invention of group I, and further selects breast cancer and CXCL9, then the claims will be examined as they

regard breast cancer and CXCL9, including SEQ ID NO: 1 but not SEQ ID NOs: 3 and 4. In the case of this requirement for further restriction, the diseases represent separate pathologies, physiologies and treatment needs, and the genetic markers represent distinct and structurally unique nucleic acid sequences, and therefore in each case the search of one would not be coextensive with the other.

3. Claims 44 and 47 link(s) inventions IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 44 and 47. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

4. Invention I is not related to inventions II and III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid based diagnostic methods of invention I

neither recite nor require the method steps of inventions II or III, and has a different mode of operation than the protein based methods of invention II, and a different function than the methods for assaying test compounds of invention III.

5. Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of invention IV can be used for a process other than disease diagnosis, for instance a probe that binds to SEQ ID NO: 1 could be used as a capture probe to affinity purify native nucleic acids, or to amplify a nucleic acid for an expression vector.

6. Invention I is unrelated to inventions V, VI, and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of invention I neither recites nor requires the kit of invention V (kits for protein based diagnosis), or the therapeutic agents of inventions VI and VII.

7. Inventions V and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of

invention V can be used for a process other than disease diagnosis, for instance a reagent that binds to a protein could be used to purify protein from cells, or to detect recombinant protein produced from an expression vector.

8. Invention II is not related to inventions III, IV, VI, and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein based diagnosing method of invention II does not require the compound testing steps of invention III, and invention II has a different function than the methods for assaying test compounds of invention III; additionally, the methods of invention II neither recite nor require the products of the kit of invention IV, or the therapeutic products of inventions VI or VII.

9. Invention III is related as product and process of use with inventions IV and V. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kits of inventions IV and V can be used in different processes, as evidenced at least by their uses in inventions I and II.

10. Inventions III is unrelated to inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method for assessing test compounds

(invention III) neither recites nor requires the specific therapeutic agents of inventions VI and VII.

11. Inventions IV, V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are used in distinct methods, have different modes of operation (inventions IV and VII are nucleic acid based; invention V and VI are protein based), and different functions (inventions IV and V are kits for diagnosing; inventions VI and VII are therapeutic agents).

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I - VII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

13. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented

prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen Kapushoc
Art Unit 1634

JULIET C. SWITZER
PRIMARY EXAMINER